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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/652,100	08/28/2003	Richard Scott Weston	BLSKY.011A	9860

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER

ANDERSON, CATHARINE L

ART UNIT	PAPER NUMBER
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3761

NOTIFICATION DATE	DELIVERY MODE
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11/13/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No.	Applicant(s)	
	10/652,100	WESTON, RICHARD SCOTT	
	Examiner	Art Unit	
	Lynne Anderson	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 and 53-68 is/are pending in the application.
- 4a) Of the above claim(s) 32-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5-31 and 53-68 is/are rejected.
- 7) ☒ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/8/08, 8/1/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1 August 2008 has been entered.

Response to Arguments

2. Applicant's arguments filed 1 August 2008 have been fully considered but they are not persuasive.

3. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the first and second materials being different types of material from one another) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

4. Since the layers of Orgill are separate layers, they comprise a first layer made up of a first material and a second layer made up of a second material. Due to the difference proximity to the wound site of the second layer, the second layer of material has a different rate of absorption of tissue than the first layer of material. Orgill therefore anticipates the present claims.

5. In response to applicant's argument that the bellows of Zamierowski are not configured to monitor the level of pressure, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Zamierowski discloses in paragraph [0054] the bellows comprising a flexible material. Therefore, the flexible bellows of Zamierowski are fully capable of being collapsed under pressure and thereby indicating a high level of pressure.

6. In response to the applicant's argument that Zamierowski fails to disclose a plurality of protrusions, it is noted that the bellows 110a of Zamierowski comprise a plurality of protrusions, as shown in figure 5a.

7. In response to applicant's argument with respect to claim 24 that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Allen teaches the use of a temperature monitor that allows for a visual indication of temperature on the outer cover of an article. The disclosure of Allen is not relied upon for the absorbent structure disclosed by Allen but only for the teaching of a color change temperature monitor that allows for a visual indication of temperature on the outer

cover. One of ordinary skill in the art would be motivated to modify the temperature change monitor disclosed by Orgill based on the teachings of Allen to provide a color change temperature monitor, since such a monitor provides the predictable result of a monitor that allows for a visual indication of temperature on the outer cover.

Claim Rejections - 35 USC § 102

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 1-2, 5, 53-57, 59, and 63-65 are rejected under 35 U.S.C. 102(e) as being anticipated by Orgill et al. (2003/0108587).

10. Orgill discloses all aspects of the claimed invention with the exception of first and second absorbable layers. Orgill discloses an appliance for administering a reduced pressure treatment to a wound, as described in paragraph [0012]. The appliance comprises a cover 115 and an absorbable matrix 105, as shown in figure 8A. The cover 115 creates a seal, as disclosed in paragraph [0040]. The matrix 105 is bio-absorbable, as disclosed in paragraph [0034], and comprises a first matrix layer 125a and 125b, as shown in figure 8B. Since first matrix layer 125a is initially located closer to the wound site, it will be absorbed at a faster rate than the second matrix layer 125b, which will not be absorbed until after the first matrix layer 125a is absorbed.

11. With respect to claim 2, the matrix 105 comprises more than one type of absorbent material, as disclosed in paragraph [0034].

12. With respect to claim 5, a segment of tubing 120 is embedded in the matrix 105, as shown in figure 5.

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13. With respect to claim 53, a port 120 supplies reduced pressure within the cover 115, as shown in figure 7A.

14. With respect to claims 54-55, a multisensor 170, as shown in figure 10A, monitors pressure and temperature, as disclosed in paragraphs [0092-0094] and figure 4.

15. With respect to claim 56, a source of suction is provided, as disclosed in paragraph [0034].

16. With respect to claims 57 and 63, a conduit 120 communicates with a source of reduced pressure.

17. With respect to claim 59, the first matrix layer 125a completely covers the bottom surface of the second matrix layer 125b, as shown in figure 8B, and therefore substantially surrounds the second layer.

18. With respect to claim 65, the second matrix layer 125b is located closer to the cover, as shown in figure 8B, and has a lower rate of absorption than the first matrix layer 125a due to its greater distance from the wound site.

19. Claims 6, 8-11, 14, 16-21, 61-62, and 66-67 are rejected under 35 U.S.C. 102(e) as being anticipated by Zamierowski et al. (2003/0050594).

20. Zamierowski discloses an appliance for treatment of a body comprising a cover 108, as shown in figure 5, and a seal, as described in paragraph [0061]. The cover 108 further comprises a projection in the form of hills or bellows 110a, as shown in figure 5A, and therefore comprises means for monitoring pressure integral with the cover. The

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cover is capable of compression to provide a visual indication of pressure, as disclosed in paragraph [0059]. The appliance further comprises a packing material 114 and an absorbable matrix 106, as shown in figure 5. A conduit 36 is in communication with a source of reduced pressure, as shown in figure 5. Each protrusion of the bellows 110a has a closed end portion, and the bellows 110a is positioned within the periphery of, and is supported by, the cover 108, as shown in figure 5A.

Claim Rejections - 35 USC § 103

21. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

22. Claims 3 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orgill et al. (2003/0108587) in view of Lockwood et al. (2002/0065494).

23. Orgill discloses all aspects of the claimed invention with the exception of an adhesive material on the cover. Lockwood teaches the use of an adhesive material on the outer edge of the cover 62 of a wound treatment appliance, as shown in figure 3. The adhesive provides for a secure attachment of the appliance to the skin of the patient. It would therefore be obvious to one of ordinary skill in the art at the time of invention to provide the cover of Orgill with an adhesive material, as taught by Lockwood, so the cover may be securely attached to a patient.

24. Claims 24-29, 60, 64, and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orgill et al. in view of Allen et al. (2003/0014025).

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25. Orgill discloses all aspects of the claimed invention with the exception of a temperature change material that changes color to indicate a change in temperature. Orgill discloses a temperature measuring means 170 measures the temperature of the wound, as disclosed in paragraph [0094]. The temperature measuring means 170 comprises a temperature-sensitive material 180 which is located between the cover 115 and wound, as shown in figure 10A, and is therefore integral with the cover.

26. Allen teaches the use of a temperature change material that signals a change in the temperature of a patient by changing color, as disclosed in paragraph [0059]. The temperature change material may be used in a bandage, as disclosed in paragraph [0014]. The temperature change material of Allen allows a user to visually detect a change in temperature of a patient due to the color change. It would therefore be obvious to one of ordinary skill in the art at the time of invention to provide the temperature sensor of Orgill with a temperature change material that changes color, as taught by Allen, to allow a user to visually detect the change in temperature.

27. Claims 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orgill et al. (2003/0108587) in view of Boynton et al. (7,004,915).

28. Orgill discloses all aspects of the claimed invention with the exception of a data processor, alarm, and display attached to the temperature measuring device. Orgill discloses the desire for a controller to monitor and control the temperature measuring device, as shown in figure 7 and described in paragraphs [0092] and [0099]. Orgill

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further discloses the importance of sensing a change in the temperature and maintaining the optimum temperature, as disclosed in paragraph [0093].

29. Boynton teaches the use of a data processor having an alarm and display for monitoring a wound treatment apparatus, as shown in figures 4a and 4b. The processor allows for feedback from the sensors to be processed and for the user to monitor and maintain the variables being measured by the sensors. It would therefore be obvious to one of ordinary skill in the art at the time of invention to provide the apparatus of Orgill with the data processing system taught by Boynton to allow for feedback from the sensors to be processed and for the user to monitor and maintain the variables being measured by the sensors.

30. Claim 58 is rejected under 35 U.S.C. 103(a) as being unpatentable over Orgill et al. (2003/0108587) in view of Johnson et al. (7,070,584).

31. Orgill discloses all aspects of the claimed invention with the exception of a third absorbable matrix layer. Johnson teaches wound dressing having three bioabsorbable matrix layers, as disclosed in Claims 8 and 11, to provide the predictable result of reducing the need to change the dressing and apply additional bioabsorbable layers. It would therefore be obvious to one of ordinary skill in the art at the time of invention to provide the wound dressing of Orgill with a third bioabsorbable matrix layer, as taught by Johnson, to provide the predictable result of reducing the need to change the dressing and apply additional bioabsorbable layers.

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32. Claims 7, 12-13, 15, and 22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zamierowski et al. (2003/0050594) in view of Lockwood et al. (2002/0065494).

33. With respect to claims 7 and 15, Zamierowski discloses all aspects of the claimed invention with the exception of an adhesive material on the cover. Lockwood teaches the use of an adhesive material on the outer edge of the cover 62 of a wound treatment appliance, as shown in figure 3. The adhesive provides for a secure attachment of the appliance to the skin of the patient. It would therefore be obvious to one of ordinary skill in the art at the time of invention to provide the cover of Zamierowski with an adhesive material, as taught by Lockwood, so the cover may be securely attached to a patient.

34. With respect to claims 12-13 and 22-23, Zamierowski discloses all aspects of the claimed invention with the exception of the pressure sensor comprising a different color or an audible sound. Use of color changes and audible alarms are well-known in the art as signaling devices. It would therefore be obvious to one of ordinary skill in the art at the time of invention to provide the appliance of Zamierowski with a different color or an audible sound, to provide a noticeable signal of a change in pressure.

Allowable Subject Matter

35. Claims 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynne Anderson whose telephone number is (571)272-4932. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. A./

Examiner, Art Unit 3761

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761